

In the Drawings

The Examiner's approval is requested to i) add numerals 46, 48, 50 and 94 in Fig. 2, ii) delete the line connecting the element 72 to the element 64 in Fig. 2, iii) add numerals 19', 46, 48 and 50 in Fig. 3, iv) change "10" to -- 10' -- in Fig. 3, v) delete the line connecting the element 72 to the element 64 in Fig. 3, vi) add numeral 158 in Fig. 9, vii) add numeral 24' in Fig. 11, viii) add numeral 12''' in Fig. 13, ix) add numeral 202 in Fig. 18, x) add numeral 162 in Fig. 19, and xi) add numeral 405 in Fig. 28, all as shown in red on the attached drawing copies. Formal drawings containing these changes will be submitted upon the Examiner's approval.

In the Claims

Amend claims 33, 45, 46, 54, 55, 58, 65-67, 74, 76 and 78 as shown in Appendix C (a marked-up copy appears in Appendix D).

Add new claim 86 as set forth in Appendix E.

REMARKS

Specification

The specification has been objected to because of certain informalities specified by the Examiner. The specification has been amended herein to correct these informalities. In addition, the specification has been amended herein to correct other minor typographical errors.

Drawing Objections

The drawings have been objected to because of certain informalities specified by the Examiner. Drawings corrections have been proposed to correct these informalities. In addition, the drawings were objected to because they include reference numbers "22" and "24", which the Examiner believed were not mentioned in the description. However, the reference numbers "22" and "24" can be found on page 7, lines 22 and 25, of the description, respectively. Also, drawings corrections have been proposed herein to provide some missing reference numbers in various figures.

Claim Objections

Claims 46 and 67 have been objected to because they contain the phrase “at least one passageways”. Claims 46 and 67 have been amended herein to change the phrase “at least one passageways” to -- at least one passageway --.

Allowable Subject Matter

The Examiner has indicated that claim 32 is allowed and claims 54, 65 and 74 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, claims 54, 65 and 74 have been rewritten as requested by the Examiner, and are believed to be allowable.

Claim Rejections - 35 U.S.C. § 102(e)

Reconsideration of the rejection of claim 33 under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,398,767 to Fleischmann (“Fleischmann”) is requested. It is believed that amended claim 33 is not anticipated by Fleischmann at least for the reasons given below.

Claim 33 is directed to a wound treatment apparatus comprising a bandage including a wound facing surface configured to face toward a wound and a fluid drainage passageway having an opening adjacent the wound facing surface, a fluid drainage tube coupled to the fluid drainage passageway, first and second fluid drainage receptacles coupled to the drainage tube, and first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.

Fleischmann does not disclose or suggest “a bandage including a wound facing surface configured to face toward a wound and a fluid drainage passageway having an opening adjacent the wound facing surface”. *Specifically*, Fleischmann’ padding 12 does not have “a fluid drainage passageway having an opening adjacent the wound facing surface”. The Examiner argues that Fleischmann’ bandage (10) (sic -- 12 --) has “a fluid drainage passageway therein for insertion of a fluid drainage tube (16).” However, as shown in Fig. 1, Fleischmann’ fluid drainage passageway in the padding 12 (into which the fluid drainage tube 16 is inserted) does not have “an opening adjacent the wound facing surface” of the padding 12. Instead, as clearly shown in Fig. 1, Fleischmann’ fluid drainage passageway in the padding 12 is spaced apart from “the wound facing surface” of the padding 12.

Second, Fleischmann does not disclose or suggest “first and second fluid drainage receptacles coupled to the drainage tube”. Instead, Fleischmann, discloses an *infusion* container 24 to which a supply line 22 is connected for supplying a fluid active substance to the wound 10 and a *receptacle* container 28 to which a removal line 26 and a vacuum source 30 is connected for suctioning off the fluid active substance and the wound secretion from the wound 10. See, for example, Fleischmann’s Fig. 1 and column 4 lines 66 et seq. The Examiner argues “that both receptacles, because of the configuration of the tubing, could be used to drain the wound.” Applicants respectfully disagree. There is no disclosure or suggestion whatsoever in Fleischmann that the *infusion* container 24 can be used “to drain the wound”. *To the contrary*, the *infusion* container 24 is placed *higher* than the wound 10 to create a certain over-pressurization when the fluid active substance is supplied to the wound 10 during the time interval T2 in Fig. 3. *Further*, not only there is no vacuum source coupled to the *infusion* container 24, Fleischmann suggests that a pressure controlled pump may be coupled to the supply line 22 to create a certain over-pressurization. See, for example, Fleischmann’s column 5, lines 45 et seq. and lines 64 et seq. Thus, using the *infusion* container 24 “to drain the wound” as suggested by the Examiner would be completely contrary to the teachings of Fleischmann.

Third, Fleischmann does not disclose or suggest “first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively”. Instead, Fleischmann’s valves 32, 34 are coupled between the drainage tube 16 and the *infusion* container 24 and the *receptacle* container 28, respectively. Accordingly, at least for these reasons, applicants respectfully submit that amended claim 33 is not anticipated by Fleischmann, and hence withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 U.S.C. § 102(b)

Reconsideration of the rejection of claims 45-47, 55 and 66-68 under 35 U.S.C. 102(b) as being anticipated by WO 91/00718 to Svedman (“Svedman”) is requested. It is believed that amended independent claims 45, 55 and 66, and dependent claims 46, 47, 67 and 68, are not anticipated by Svedman at least for the reasons given below.

Amended independent claim 45 is directed to a wound treatment apparatus comprising a negative pressure source, a fluid source and a bandage configured to cover a wound and adhere to healthy skin adjacent the wound. The bandage comprises a sheet overlying the wound and located adjacent to it. The sheet has a plurality of discrete

passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.

Svedman does not disclose or suggest a bandage comprising “a sheet overlying the wound and located adjacent to it,” in combination with “the sheet having a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.” Instead, as clearly shown in Figs. 1, 3-7, 8, 9 and 10a and described at page 3, lines 32 et seq., Svedman’s flexible plate 1 is spaced apart from the wound, and a conduit 10 extends between a perforation in the flexible plate 1 attached to a patient’s skin and a padding 11 located in the wound cavity. Accordingly, at least for these reasons, applicants respectfully submit that amended independent claim 45, and dependent claims 46 and 47, are not anticipated by Svedman. Likewise, amended independent claims 55 and 66, and dependent claims 67 and 68, are not anticipated by Svedman for the reasons given above in support of amended independent claim 45. Withdrawal of 35 U.S.C. 102(b) rejection of claims 45-47, 55 and 66-68 is therefore respectfully requested.

Claim Rejections - 35 U.S.C. § 103(a)

Reconsideration of the rejection of claims 33-35 as being unpatentable under 35 U.S.C. 103(a) over GB. Pat. No. 1,549,756 to Westaby et al. (“Westaby”) in view of Fleischmann is requested. It is believed that amended independent claim 33, and dependent claims 34 and 35, patentably distinguish over Westaby and Fleischmann at least for the reasons given below.

With regard to amended independent claim 33, Examiner agrees that Westaby does not disclose or suggest “first and second fluid drainage receptacles coupled to the drainage tube” and “first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively”. However, the Examiner argues that Fleischmann discloses “first and second fluid drainage receptacles coupled to the drainage tube” and “first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively”. Applicants respectfully disagree.

As indicated above, Fleischmann does not disclose or suggest “first and second fluid drainage receptacles coupled to the drainage tube”. Instead, Fleischmann, discloses an *infusion* container 24 to which a supply line 22 is connected for supplying a fluid

active substance to the wound 10 and a *receptacle* container 28 to which a removal line 26 and a vacuum source 30 is connected for suctioning off the fluid active substance and the wound secretion from the wound 10. See, for example, Fleischmann's Fig. 1 and column 4 lines 66 et seq. The Examiner argues "that both receptacles, because of the configuration of the tubing, could be used to drain the wound." This is not correct. There is no disclosure or suggestion whatsoever in Fleischmann that the *infusion* container 24 can be used "to drain the wound". *To the contrary*, the *infusion* container 24 is placed *higher* than the wound 10 to create a certain over-pressurization when the fluid active substance is supplied to the wound 10 during the time interval T2 in Fig. 3. *Further*, not only there is no vacuum source coupled to the *infusion* container 24, Fleischmann suggests that a pressure controlled pump coupled to the supply line 22 may be used to create a certain over-pressurization. See, for example, Fleischmann's column 5, lines 45 et seq. and lines 64 et seq. Thus, using the *infusion* container 24 "to drain the wound" as suggested by the Examiner would be completely contrary to the teachings of Fleischmann.

Second, Fleischmann does not disclose or suggest "first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively". Instead, Fleischmann's valves 32, 34 are coupled between the drainage tube 16 and the *infusion* container 24 and the *receptacle* container 28, respectively. Accordingly, at least for these reasons, applicants respectfully submit that amended independent claim 33, and dependent claims 34 and 35, patentably distinguish over Westaby and Fleischmann, and hence withdrawal of this rejection is respectfully requested.

Further, in addition to failing to disclose or teach each of the elements of the parent claim 33, neither Westaby nor Fleischmann disclose or teach the limitations of the dependent claim 35 - *namely*, "a sensor coupled to the first fluid drainage receptacle to provide a signal indicative of an amount of fluid in the receptacle". The Examiner has contended that "sensors of all kinds are well known in the art, and the addition of such to ... either Westaby et al. or Fleischmann would only include routine skill in the art." If such addition only involved routine skill in the art as the Examiner has contended, then the Examiner should be able to provide evidence thereof. However, the Examiner has offered no basis for his assertion. There is no teaching whatsoever in either Westaby or Fleischmann of applicants' limitation - *namely*, "a sensor coupled to the first fluid drainage receptacle to provide a signal indicative of an amount of fluid in the receptacle". Withdrawal of 35 U.S.C. 103(a) rejection of claim 35 is therefore respectfully requested.

Reconsideration of the rejection of claims 45, 49-53, 55-57, 60-62, 64, 66, 60 (sic -- 69 --)-73, 76, 77 (sic -- 75-77 --), 80-83 and 85 as being unpatentable under 35 U.S.C. 103(a) over Westaby is requested. It is believed that amended independent claims 45, 55, 66 and 76, and dependent claims 49-53, 56, 57, 60-62, 64, 69-73, 75, 77, 80-83 and 85, patentably distinguish over Westaby at least for the reasons given below.

Amended independent claim 45 is directed to a wound treatment apparatus comprising a negative pressure source, a fluid source and a bandage configured to cover a wound and adhere to healthy skin adjacent the wound. The bandage comprises a sheet overlying the wound and located adjacent to it. The sheet has a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.

Westaby does not disclose or suggest a bandage comprising “a sheet overlying the wound and located adjacent to it” in combination with “the sheet having a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.” Instead, as clearly shown in Figs. 2 and 3 and described at column 2 (left side), lines 40 et seq., Westaby’s cover 10 overlying the wound 12 is domed to enclose a cavity *beneath* it and *above* the wound 12. In other words, a cavity is located between the cover 10 and the wound 12, and the cover 10 overlying the wound is not “located adjacent to it”. Accordingly, at least for these reasons, applicants respectfully submit that amended independent claim 45, and dependent claims 49-53, patentably distinguish over Westaby. Likewise, amended independent claims 55, 66 and 76, and dependent claims 56, 57, 60-62, 64, 69-73, 75, 77, 80-83 and 85, patentably distinguish over Westaby for the reasons given above in support of amended independent claim 45. Withdrawal of 35 U.S.C. 103(a) rejection of claims 45, 49-53, 55-57, 60-62, 64, 66, 69-73, 75-77, 80-83 and 85 is therefore respectfully requested.

Reconsideration of the rejection of claims 48 and 63 as being unpatentable under 35 U.S.C. 103(a) over Westaby in view of U.S. Pat. No. 6,142,982 to Hunt et al. (“Hunt”) is requested. It is believed that claims 48 and 63 patentably distinguish over Westaby and Hunt at least for the reasons given below.

Claims 48 and 63 depend from amended claims 45 and 55, respectively, and therefore patentably distinguish over Westaby for the reasons given above in support of

amended claims 45 and 55. *For example*, Westaby does not disclose or suggest a bandage comprising “a sheet overlying the wound and located adjacent to it” in combination with “the sheet having a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.” Instead, as clearly shown in Figs. 2 and 3 and described at column 2 (left side), lines 40 et seq., Westaby’s cover 10 overlying the wound 12 is domed to enclose a cavity *beneath* it and *above* the wound 12. In other words, a cavity is located between the cover 10 and the wound 12, and the cover 10 overlying the wound is not “located adjacent to it”.

Further, Hunt is neither proffered for, nor does it overcome the above-mentioned deficiencies of Westaby. For example, Hunt does not disclose or suggest a bandage comprising “a sheet overlying the wound and located adjacent to it” in combination with “the sheet having a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound”. Therefore, applicants submit that claims 48 and 63 patentably distinguish over Westaby and Hunt, and hence withdrawal of this rejection is respectfully requested.

Reconsideration of the rejection of claims 55, 58, 59, 76, 78 and 79 as being unpatentable under 35 U.S.C. 103(a) over U.S. Pat. No. 4,953,565 to Tachibana et al. (“Tachibana”) is requested. It is believed that amended independent claims 55 and 76, and dependent claims 58, 59, 78 and 79, patentably distinguish over Tachibana for the reasons given below.

Amended independent claim 55 is directed to a wound treatment apparatus comprising a fluid source, a negative pressure source and a bandage configured to cover a wound and adhere to healthy skin adjacent the wound. The bandage comprises a sheet overlying the wound and located adjacent to it. The sheet has a plurality of discrete apertures. Fluid from the fluid source is communicated to the wound through at least a first aperture of the plurality of discrete apertures, and the negative pressure is communicated to the wound through at least a second aperture of the plurality of discrete apertures.

Tachibana does not disclose or suggest a bandage comprising “a sheet overlying the wound and located adjacent to it” in combination with “the sheet having a plurality of discrete apertures” and “fluid from the fluid source being communicated to the wound through at least a first aperture of the plurality of discrete apertures, and negative

pressure being communicated to the wound through at least a second aperture of the plurality of discrete apertures”. The Examiner has argued that Tachibana discloses “a device capable of treating a wound comprising a first sheet/bandage (11) having a plurality of apertures/passageways through which the fluid delivery conduits and fluid drainage conduits are inserted”. However, as clearly shown in Figs. 1 and 2 and described at column 2, lines 60 et seq. and column 3 lines 40 et seq., Tachibana’s container 11, 11’ overlying the wound is domed to form a cavity *beneath* it and *above* the wound to make space for an ultrasonic oscillator 10, 25. In other words, a cavity containing an ultrasonic oscillator 10, 25 is located between the container 11, 11’ and the wound, and the container 11, 11’ overlying the wound is not “located adjacent to it”. Accordingly, at least for these reasons, applicants respectfully submit that amended independent claim 55, and dependent claims 58, 59, patentably distinguish over Tachibana. Withdrawal of 35 U.S.C. 103(a) rejection of claims 55, 58 and 59 is therefore respectfully requested.

Amended independent claim 76 is directed to a bandage for use with a wound treatment apparatus having a negative pressure source. The bandage comprises a sheet overlying a wound and located adjacent to it, the sheet having a plurality of discrete apertures adapted to communicate negative pressure established by the negative pressure source to the wound. Tachibana does not disclose or suggest a bandage comprising “a sheet overlying a wound and located adjacent to it” in combination with “the sheet having a plurality of discrete apertures adapted to communicate negative pressure established by the negative pressure source to the wound”. As indicated above, in Tachibana, a cavity containing an ultrasonic oscillator 10, 25 is located between the container 11, 11’ and the wound, and the container 11, 11’ overlying the wound is not “located adjacent to it”. Accordingly, at least for these reasons, applicants respectfully submit that amended independent claim 76, and dependent claims 78, 79, patentably distinguish over Tachibana. Withdrawal of 35 U.S.C. 103(a) rejection of claims 76, 78 and 79 is therefore respectfully requested.

Further, in addition to failing to disclose or teach each of the elements of the parent claims 55 and 76, Tachibana does not disclose or teach the limitations of the amended dependent claims 58 and 78 - *namely*, “the bandage comprises a second sheet coupled to the first sheet and the second sheet has at least one discrete aperture, but has a lesser number of discrete apertures than the first sheet”. The Examiner has agreed that the second sheet 14, 14’ does not have any apertures. Accordingly, in addition to the reasons given above in support of amended parent claims 55 and 76, applicants respectfully submit that amended dependent

claims 58 and 78 patentably distinguish over Tachibana for the reasons given above in this paragraph.

Double Patenting Rejection

Claims 45, 49-52, 55, 57, 61, 62, 66, 69-72, 75-77, 80-82 and 85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 24, 25, 28 and 37 of U. S. Patent No. 6,458,109. A terminal disclaimer is submitted herewith in compliance with 37 C.F.R. 1.321(c) to overcome the double patenting rejection.

New Claim

New claim 86 is believed to be allowable because none of the cited art teach or fairly suggest the limitations of new claim - *namely*, “first and second fluid drainage receptacles coupled to the drainage tube; and first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.”

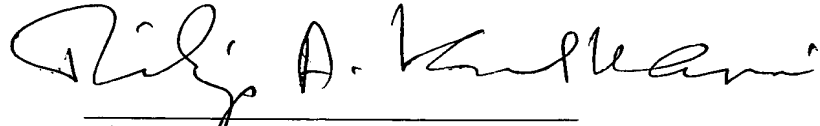
Further Action

In view of the foregoing amendment and supporting remarks, the subject application is now deemed to be in condition for allowance, and such action is respectfully requested. If the Examiner believes that a telephonic interview would expedite the allowance of this application, he is requested to contact the undersigned for a prompt resolution of any outstanding issues.

It is respectfully requested, if necessary to effect a timely response, that this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages and other fees be charged, or any overpayment in fees be credited, to

the Account of Barnes & Thornburg, Deposit Account No. 10-0435, with reference to file 7175- 67612. A duplicate copy of this authorization is enclosed.

Respectfully submitted,
BARNES & THORNBURG

A handwritten signature in black ink, appearing to read "Dilip A. Kulkarni", written over a horizontal line.

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Appendix A to Response

Clean Copy of Rewritten Paragraphs

Application No. 09/743,737 (filed January 16, 2001)

1. *Please replace the paragraph beginning at page 6, line 28, as set forth below:*

A1 Referring now to the drawings, Fig. 1 illustrates a wound treatment apparatus 10 that includes a bandage assembly 12 coupled to a patient's skin 14 adjacent a surface wound 16. Apparatus 10 includes a wound temperature control system 17, a wound drainage system 19, and a medicinal fluid supply system 15 including a nebulizer 26 shown in Figs. 2 and 3. Wound treatment apparatus 10 provides a system for controlling the topical atmosphere adjacent wound 16, including delivery of medication, control of atmospheric constituents, temperature regulation, and collection of wound drainage.

2. *Please replace the paragraph beginning at page 7, line 22, as set forth below:*

A2 Delivery bandage 18 includes a medicinal fluid supply tube 22 and is coupled to the patient's skin 14 over wound 16. Delivery bandage 18 can remain in place while drainage bandage 20 can be changed as needed during wound treatment. Drainage bandage 20 includes a wound drainage tube 24 that is coupled to wound 16 through delivery bandage 18 to allow fluid from wound 16 to exit from bandage assembly 12, the fluid including both fluids secreted by wound 16 as well as fluids entering bandage 18 through medicinal fluid supply tube 22. Bandage assembly 12 thus allows control of the topical atmosphere adjacent wound 16 while limiting the exposure to atmospheric contaminants, allowing for use of treatment protocols to enhance healing while reducing opportunities for potential infection and trauma.

3. *Please replace the paragraph beginning at page 8, line 16, as set forth below:*

A3 Nebulizer output port 30 is coupled to medicinal fluid supply tube 22 of delivery bandage 18 of bandage assembly 12. Optionally, a liquid medication pump 39 such as an IV pump can also be coupled to medicinal fluid supply tube 22. Wound treatment apparatus 10 thus provides for delivery of either aerosol or liquid medication or both to wound 16 through delivery bandage 18.

4. Please replace the paragraph beginning at page 10, line 5, as set forth below:

A4
Oxygen input port 50 can illustratively be coupled to a standard hospital oxygen blender 62 through a standard hospital air filter and water trap 64. An internal compressed oxygen supply (not shown) can replace oxygen blender 62. Oxygen filter and water trap 64 contains a 5 micron filter element and catch basin to trap particulate matter and condensed water output from oxygen blender 62. Blender 62 further illustratively includes an oxygen flowmeter 66 such as a standard hospital pediatric flowmeter that allows a flow set range of, for example, between zero and three liters per minute.

5. Please replace the paragraph beginning at page 11, line 5, as set forth below:

A5
Nebulizer gas input assembly 46 further includes an air pressure sensor 74 coupled between selector valve 58 and air pressure regulator 54, an oxygen pressure sensor 76 coupled between selector valve 58 and oxygen pressure regulator 56, and a nebulizer gas input pressure sensor 80 coupled between selector valve 58 and nebulizer input port 28. Sensors 74, 76, 80 are coupled to control system 44 to provide feedback for monitoring of proper system operation and so that an alarm can be indicated and wound treatment apparatus 10 shut down automatically if a pressure signal exceeds a predetermined threshold.

6. Please replace the paragraph beginning at page 11, line 22, as set forth below:

A6
Wound treatment apparatus 10 further includes a nebulizer pressure sensor 80 coupled between selector valve 58 and nebulizer input port 28. Pressure sensor 80 provides a feedback signal to control system 44 indicative of pressure within nebulizer 26 and is also used to verify the proper operation of selector valve 58. Wound treatment apparatus 10 furthermore includes a tilt sensor 82 and a bandage interface pressure sensor 84, both coupled to control system 44. Tilt sensor 82 signals an alarm and shuts down apparatus 10 if apparatus 10 is tilted beyond a predetermined threshold, illustratively 30°.

7. Please replace the paragraph beginning at page 14, line 9, as set forth below:

A7
Delivery bandage top sheet 104 is formed to include a perimeter 124, tab 126, central passageway 128, and outer passageways 130 that are configured to align with perimeter 112, tab 116, central passageway 118, and outer passageways 122 of bottom sheet 102 as best shown in Fig. 6. When top and bottom sheets 102, 104 are aligned, central

A7
Cont'd
passageways 118, 128 and outer passageways 122, 130 are in fluid communication and allow wound effluent to pass through bandage 18.

8. Please replace the paragraph beginning at page 20, line 17, as set forth below:

A8
Fluid junction array 330 attaches to adhesive 361 which adheres to a portion of healthy tissue surrounding wound 16. It is appreciated, however, that array 330 may be attached to the skin by any variety of suitable means. Top sheet 362 is sized to cover apparatus 320 and may be removably attached directly to healthy skin (not shown). Top sheet 362 is illustratively formed from a clear, flexible polyurethane or vinyl that meets USP Class VI requirements for medical applications. Gasket or border 360 is illustratively formed with a generally square perimeter having rounded corners attaching to the skin about the periphery of tube 344 and serves as a seal. In one embodiment, border 360 is positioned underneath top sheet 362, as shown in Fig. 21. In addition, border 360 attaches to array 330 by a pair of fasteners 364 that extend through apertures 366.

9. Please replace the paragraph beginning at page 20, line 28, as set forth below:

A9
Another embodiment of the wound treatment apparatus is indicated by reference number 368 and is shown in Figs. 23 and 24. A fluid supply tube 382 leads illustratively into outer chamber 378. Outer chamber 378 is formed about the periphery of inner chamber 374. Chambers 374 and 378 are formed by a top sheet and a bottom sheet 372 and 373, respectively. (See Fig. 24.) Illustratively, RF welds about the periphery of inner chamber 374 and about the periphery of outer chamber 378 further defines the chambers within sheets 372 and 373. The welds form an inner border and an outer border 375 and 380, respectively. It is understood that any suitable means can be used to form borders 375 and 380, in place of ultra-sonic welds. For example, borders 375 and 380 can be made from adhesive or from heat selectively applied to sheets 372 and 373.

10. Please replace the paragraph beginning at page 22, line 26, as set forth below:

C10
An additional embodiment of a wound treatment apparatus is indicated by reference number 392 and is shown in Figs. 27-29. Wound apparatus 392 comprises a fluid supply tube 396 extending illustratively near the center of apparatus 392 into a dispensing aperture 398. Aperture 398 opens to a wound cavity 400 formed on the underside of apparatus 392. (See Figs. 28 and 29.) Above wound cavity 400 and formed about dispensing

aperture 398 is basin 402. Basin 402 is defined by inner and outer walls 410 and 412, respectively. Inner wall 410 separates the basin 402 from dispensing aperture 398. Outer wall 412 illustratively defines the periphery of basin 402. Columns 404 extend from basin 402, illustratively in a circular formation about inner wall 410, as shown in Fig. 27. A top sheet 405 is formed over basin 402, attaching illustratively to the top of outer wall 412. Columns 404 support top sheet 405 over basin 402. Top sheet 405 is thereby prevented from collapsing in on basin 402 and covering passageways 406 as a negative pressure is applied to bandage 392.

11. *Please replace the paragraph beginning at page 23, line 22, as set forth below:*

311 Another embodiment of the present invention includes a flexible wound treatment apparatus 420 shown in Figs. 30-32. An inlet tube 382 is extended through top panel 422 into chamber 424. Chamber 424 is formed between top panel 422, mid-panel 426, and is defined by inner and outer borders 375 and 380, respectively. (See Figs. 30 and 31.) Illustratively, an RF weld about the peripheries of chamber 424 forms borders 375 and 380 as previously discussed. Several apertures 377 are disposed through mid-panel 426 into an expanded wound cavity 428. Wound cavity 428 is defined by two laterally spaced side walls 430 and 432 and two end walls 434 and 436 extending between said side walls 430 and 432. Mid-panel 426 interconnects to the coplanar edges of walls 430, 432, 434, and 436. The resultant form is a flexible bellow or flexible body. A spacer 442 is fitted within the periphery of wound cavity 440. Spacer 442 is illustratively made from a foam material but it is understood that it can be made from any suitable material that will assist in maintaining the form of the expanded wound cavity 428 as shown in Figs. 31 and 32.

Appendix B to Response

Marked-up Copy of Rewritten Paragraphs

Application No. 09/743,737 (filed January 16, 2001)

1. *A marked-up copy of the paragraph beginning at page 6, line 28, is given below:*

Referring now to the drawings, Fig. 1 illustrates a wound treatment apparatus 10 that includes a bandage assembly 12 coupled to a patient's skin 14 adjacent a surface wound 16. Apparatus 10 includes a wound temperature control system 17, a wound drainage system 19, and a medicinal fluid supply system 15 including a nebulizer 26 shown in Figs. 2 and 3. Wound treatment apparatus 10 provides a system for controlling the topical atmosphere adjacent wound 16, including delivery of medication, control of atmospheric constituents, temperature regulation, and collection of wound drainage.

2. *A marked-up copy of the paragraph beginning at page 7, line 22, is given below:*

Delivery bandage 18 includes a medicinal fluid supply tube 22 and is coupled to the patient's skin 14 over wound 16. Delivery bandage 18 can remain in place while drainage bandage 20 can be changed as needed during wound treatment. Drainage bandage 20 includes a wound drainage tube 24 that is coupled to wound 16 through delivery bandage 18 to allow fluid from wound 16 to exit from bandage assembly 12, the fluid including both fluids secreted by wound 16 as well as fluids entering bandage 18 through medicinal fluid supply tube 22. Bandage assembly 12 thus allows control of the topical atmosphere adjacent wound [14] 16 while limiting the exposure to atmospheric contaminants, allowing for use of treatment protocols to enhance healing while reducing opportunities for potential infection and trauma.

3. *A marked-up copy of the paragraph beginning at page 8, line 16, is given below:*

Nebulizer output port [28] 30 is coupled to medicinal fluid supply tube 22 of delivery bandage 18 of bandage assembly 12. Optionally, a liquid medication pump 39 such as an IV pump can also be coupled to medicinal fluid supply tube 22. Wound treatment apparatus 10 thus provides for delivery of either aerosol or liquid medication or both to wound 16 through delivery bandage 18.

4. *A marked-up copy of the paragraph beginning at page 10, line 5, is given below:*

Oxygen input port [48] 50 can illustratively be coupled to a standard hospital oxygen blender 62 through a standard hospital air filter and water trap 64. An internal compressed oxygen supply (not shown) can replace oxygen blender 62. Oxygen filter and water trap 64 contains a 5 micron filter element and catch basin to trap particulate matter and condensed water output from oxygen blender 62. Blender 62 further illustratively includes an oxygen flowmeter 66 such as a standard hospital pediatric flowmeter that allows a flow set range of, for example, between zero and three liters per minute.

5. *A marked-up copy of the paragraph beginning at page 11, line 5, is given below:*

Nebulizer gas input assembly 46 further includes an air pressure sensor [68] 74 coupled between selector valve 58 and air pressure regulator 54, an oxygen pressure sensor [74] 76 coupled between selector valve 58 and oxygen pressure regulator 56, and a nebulizer gas input pressure sensor [76] 80 coupled between selector valve 58 and nebulizer input port 28. Sensors [72,] 74, 76, 80 are coupled to control system 44 to provide feedback for monitoring of proper system operation and so that an alarm can be indicated and wound treatment apparatus 10 shut down automatically if a pressure signal exceeds a predetermined threshold.

6. *A marked-up copy of the paragraph beginning at page 11, line 22, is given below:*

Wound treatment apparatus 10 further includes a nebulizer pressure sensor 80 coupled between selector valve [60] 58 and nebulizer input port 28. Pressure sensor 80 provides a feedback signal to control system 44 indicative of pressure within nebulizer 26 and is also used to verify the proper operation of selector valve [60] 58. Wound treatment apparatus 10 furthermore includes a tilt sensor 82 and a bandage interface pressure sensor 84, both coupled to control system 44. Tilt sensor 82 signals an alarm and shuts down apparatus 10 if apparatus 10 is tilted beyond a predetermined threshold, illustratively 30°.

7. *A marked-up copy of the paragraph beginning at page 14, line 9, is given below:*

Delivery bandage top sheet 104 is formed to include a perimeter 124, tab 126, central passageway 128, and outer passageways 130 that are configured to align with perimeter 112, tab 116, central passageway [128] 118, and outer passageways 122 of bottom

sheet 102 as best shown in Fig. 6. When top and bottom sheets 102, 104 are aligned, central passageways 118, 128 and outer passageways 122, 130 are in fluid communication and allow wound effluent to pass through bandage 18.

8. *A marked-up copy of the paragraph beginning at page 20, line 17, is given below:*

Fluid junction array 330 attaches to adhesive 361 which adheres to a portion of healthy tissue surrounding wound 16. It is appreciated, however, that array 330 may be attached to the skin by any variety of suitable means. Top sheet 362 is sized to cover apparatus 320 and may be removably attached directly to healthy skin (not shown). Top sheet 362 is illustratively formed from a clear, flexible polyurethane or vinyl that meets USP Class VI requirements for medical applications. Gasket or border 360 is illustratively formed with a generally square perimeter having rounded corners attaching to the skin about the periphery of tube 344 and serves as a seal. In one embodiment, border 360 is positioned underneath top sheet 362, as shown in Fig. 21. In addition, border 360 attaches to array 330 by a pair of fasteners 364 that extend through apertures 366.

9. *A marked-up copy of the paragraph beginning at page 20, line 28 , is given below:*

Another embodiment of the wound treatment apparatus is indicated by reference number 368 and is shown in Figs. 23 and 24. A fluid supply tube 382 leads illustratively into outer chamber 378. Outer chamber 378 is formed about the periphery of inner chamber 374. Chambers 374 and 378 are formed by a top sheet and a bottom sheet 372 and 373, respectively. (See Fig. 24.) Illustratively, RF welds about the periphery of inner chamber 374 and about the periphery of outer chamber 378 further defines the chambers within sheets [272] 372 and [273] 373. The welds form an inner border and an outer border 375 and 380, respectively. It is understood that any suitable means can be used to form borders 375 and 380, in place of ultra-sonic welds. For example, borders 375 and 380 can be made from adhesive or from heat selectively applied to sheets 372 and 373.

10. *A marked-up copy of the paragraph beginning at page 22, line 26 , is given below:*

An additional embodiment of a wound treatment apparatus is indicated by reference number 392 and is shown in Figs. 27-29. Wound apparatus 392 comprises a fluid supply tube 396 extending illustratively near the center of apparatus 392 into a dispensing aperture 398. Aperture 398 opens to a wound cavity 400 formed on the underside of

apparatus 392. (See Figs. 28 and 29.) Above wound cavity 400 and formed about dispensing aperture 398 is basin 402. Basin 402 is defined by inner and outer walls 410 and 412, respectively. Inner wall 410 separates the basin 402 from dispensing aperture 398. Outer wall 412 illustratively defines the periphery of basin 402. Columns 404 extend from basin 402, illustratively in a circular formation about inner wall 410, as shown in Fig. 27. A top sheet 405 is formed over basin 402, attaching illustratively to the top of outer wall 412. Columns 404 support top sheet 405 over basin 402. Top sheet 405 is thereby prevented from collapsing in on basin [404] 402 and covering passageways 406 as a negative pressure is applied to bandage 392.

11. *A marked-up copy of the paragraph beginning at page 23, line 22 , is given below:*

Another embodiment of the present invention includes a flexible wound treatment apparatus 420 shown in Figs. 30-32. An inlet tube 382 is extended through top panel 422 into chamber 424. Chamber 424 is formed between top panel 422, mid-panel 426, and is defined by inner and outer borders 375 and 380, respectively. (See Figs. 30 and 31.) Illustratively, an RF weld about the peripheries of chamber 424 forms borders 375 and 380 as previously discussed. Several apertures 377 are disposed through mid-panel 426 into an expanded wound cavity 428. Wound cavity 428 is defined by two laterally spaced side walls 430 and 432 and two end walls 434 and 436 extending between said side walls 430 and 432. Mid-panel 426 interconnects to the coplanar edges of walls 430, 432, 434, and 436. The resultant form is a flexible bellow or flexible body. A spacer 442 is fitted within the periphery of wound cavity 440. Spacer 442 is illustratively made from a foam material but it is understood that it can be made from any suitable material that will assist in maintaining the form of the expanded wound cavity 428 as shown in Figs. 31 and 32.

Appendix C to Response

Clean Copy of Rewritten Claims 33, 45, 46, 54, 55, 58, 65-67, 74, 76 and 78

Application No. 09/743,737 (filed January 16, 2001)

33.(Once Amended) A wound treatment apparatus comprising:

a bandage including a wound facing surface configured to face toward a wound and a fluid drainage passageway having an opening adjacent the wound facing surface;

a fluid drainage tube coupled to the fluid drainage passageway;

first and second fluid drainage receptacles coupled to the drainage tube; and

first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.

45.(Once Amended) A wound treatment apparatus comprising

a negative pressure source,

a fluid source,

a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a sheet overlying the wound and located adjacent to it, the sheet having a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.

46.(Once Amended) The wound treatment apparatus of claim 45, wherein the bandage comprises a second sheet with at least one discrete passageway that communicates with at least one of the plurality of discrete passageways of the first sheet.

54.(Once Amended) A wound treatment apparatus comprising

a negative pressure source,

a fluid source, and

a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a first sheet with a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound, a second sheet coupled to the first sheet, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound.

55.(Once Amended) A wound treatment apparatus comprising
a fluid source,
a negative pressure source,
a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a sheet overlying the wound and located adjacent to it, the sheet having a plurality of discrete apertures, fluid from the fluid source being communicated to the wound through at least a first aperture of the plurality of discrete apertures, and negative pressure being communicated to the wound through at least a second aperture of the plurality of discrete apertures.

58.(Once Amended) The wound treatment apparatus of claim 55, wherein the bandage comprises a second sheet coupled to the first sheet and the second sheet has at least one discrete aperture, but has a lesser number of discrete apertures than the first sheet.

65.(Once Amended) A wound treatment apparatus comprising
a fluid source,
a negative pressure source, and
a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a first sheet with a plurality of discrete apertures, a second sheet coupled to the first sheet, fluid from the fluid source being communicated to the wound through at least a first aperture of the plurality of discrete apertures, and negative pressure being communicated to the wound through at least a second aperture of the plurality of discrete apertures, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound.

66.(Once Amended) A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a sheet overlying a wound and located adjacent to it, the sheet having a plurality of discrete passageways adapted to communicate negative pressure established by the negative pressure source to the wound.

67.(Once Amended) The bandage of claim 66, further comprising a second sheet with at least one discrete passageway that communicates with at least one of the plurality of discrete passageways of the first sheet.

74.(Once Amended) A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a first sheet with a plurality of discrete passageways adapted to communicate negative pressure established by the negative

pressure source to a wound, a second sheet coupled to the first sheet, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound.

76.(Once Amended) A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a sheet overlying a wound and located adjacent to it, the sheet having a plurality of discrete apertures adapted to communicate negative pressure established by the negative pressure source to the wound.

78.(Once Amended) The bandage of claim 76, wherein the bandage comprises a second sheet coupled to the first sheet and the second sheet has at least one discrete aperture, but has a lesser number of discrete apertures than the first sheet.

Appendix D to Response

Marked-up Copy of Rewritten Claims 33, 45, 46, 54, 55, 58, 65-67, 74, 76 and 78

Application No. 09/743,737 (filed January 16, 2001)

33.(Once Amended) A wound treatment apparatus comprising:

a bandage including a wound facing surface configured to face toward [the] a wound and a fluid drainage passageway having an opening adjacent the wound facing surface;

a fluid drainage tube coupled to the fluid drainage passageway;

first and second fluid drainage receptacles coupled to the drainage tube; and

first and second valves coupled between the fluid drainage tube and the first and second fluid drainage receptacles, respectively.

45.(Once Amended) A wound treatment apparatus comprising

a negative pressure source,

a fluid source,

a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a sheet overlying the wound and located adjacent to it, the sheet having [with] a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound.

46.(Once Amended) The wound treatment apparatus of claim 45, wherein the bandage comprises a second sheet with at least one discrete passageway[s] that communicates with at least one of the plurality of discrete passageways of the first sheet.

54.(Once Amended) [The wound treatment apparatus of claim 45, wherein the bandage comprises] A wound treatment apparatus comprising

a negative pressure source,

a fluid source, and

a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a first sheet with a plurality of discrete passageways through which negative pressure established by the negative pressure source is communicated to the wound and through which fluid from the fluid source is communicated to the wound, a second sheet coupled to the first sheet, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound [, the bandage comprises a second sheet, the first sheet is coupled to the second sheet, and the second sheet is coupled to the element].

55.(Once Amended) A wound treatment apparatus comprising
a fluid source,
a negative pressure source,
a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a sheet overlying the wound and located adjacent to it, the sheet having [with] a plurality of discrete apertures, fluid from the fluid source being communicated to the wound through at least a first aperture of the plurality of discrete apertures, and negative pressure being communicated to the wound through at least a second aperture of the plurality of discrete apertures.

58.(Once Amended) The wound treatment apparatus of claim 55, wherein the bandage comprises a second sheet coupled to the first sheet and the second sheet has at least one discrete aperture, but has a lesser number of discrete apertures than the first sheet.

65.(Once Amended) [The wound treatment apparatus of claim 55, wherein the bandage comprises] A wound treatment apparatus comprising
a fluid source,
a negative pressure source, and
a bandage configured to cover a wound and adhere to healthy skin adjacent the wound, the bandage comprising a first sheet with a plurality of discrete apertures, a second sheet coupled to the first sheet, fluid from the fluid source being communicated to the wound through at least a first aperture of the plurality of discrete apertures, and negative pressure being communicated to the wound through at least a second aperture of the plurality of discrete apertures, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound [, the bandage comprises a second sheet, the first sheet is coupled to the second sheet, and the second sheet is coupled to the element].

66.(Once Amended) A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a sheet overlying a wound and located adjacent to it, the sheet having [with] a plurality of discrete passageways adapted to communicate negative pressure established by the negative pressure source to the wound.

67.(Once Amended) The bandage of claim 66, further comprising a second sheet with at least one discrete passageway[s] that communicates with at least one of the plurality of discrete passageways of the first sheet.

74.(Once Amended) [The bandage of claim 66, further comprising] A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a first sheet with a plurality of discrete passageways adapted to communicate negative pressure established by the negative pressure source to a wound, a second sheet coupled to the first sheet, and an element coupled to the second sheet that adheres to healthy skin adjacent the wound [, the bandage comprising a second sheet, the first sheet being coupled to the second sheet, and the second sheet being coupled to the element].

76.(Once Amended) A bandage for use with a wound treatment apparatus having a negative pressure source, the bandage comprising a sheet overlying a wound and located adjacent to it, the sheet having [with] a plurality of discrete apertures adapted to communicate negative pressure established by the negative pressure source to the wound.

78.(Once Amended) The bandage of claim 76, wherein the bandage comprises a second sheet coupled to the first sheet and the second sheet has at least one discrete aperture, but has a lesser number of discrete apertures than the first sheet.

Appendix E to Response

New Claims

Application No. 09/743,737 (filed January 16, 2001)

86.(New Claim) A wound treatment apparatus comprising:
a bandage including a fluid drainage tube coupled to a fluid drainage cavity;
first and second fluid drainage receptacles coupled to the drainage tube; and
first and second valves coupled between the fluid drainage tube and the first
and second fluid drainage receptacles, respectively.

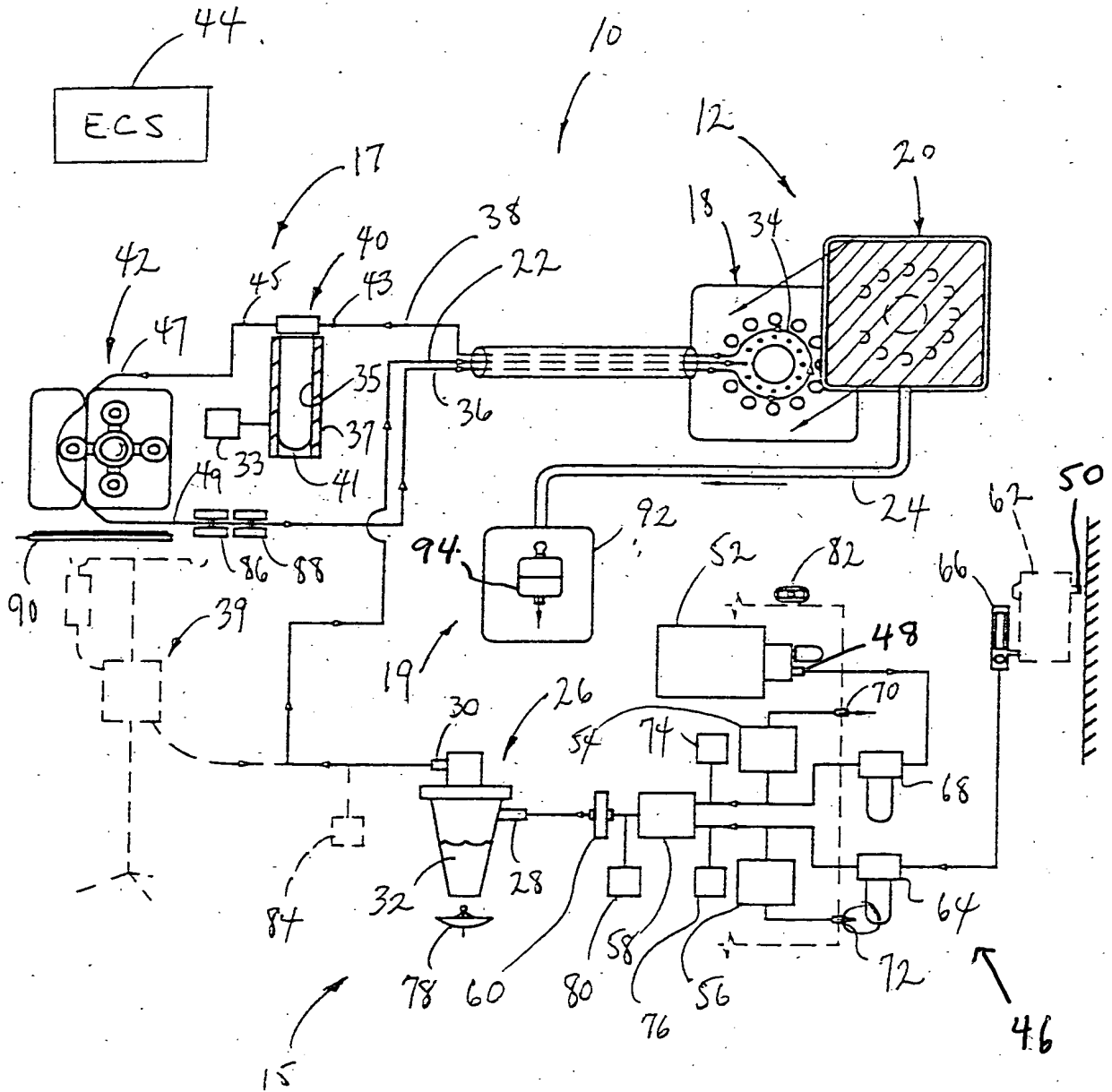


Fig. 2.

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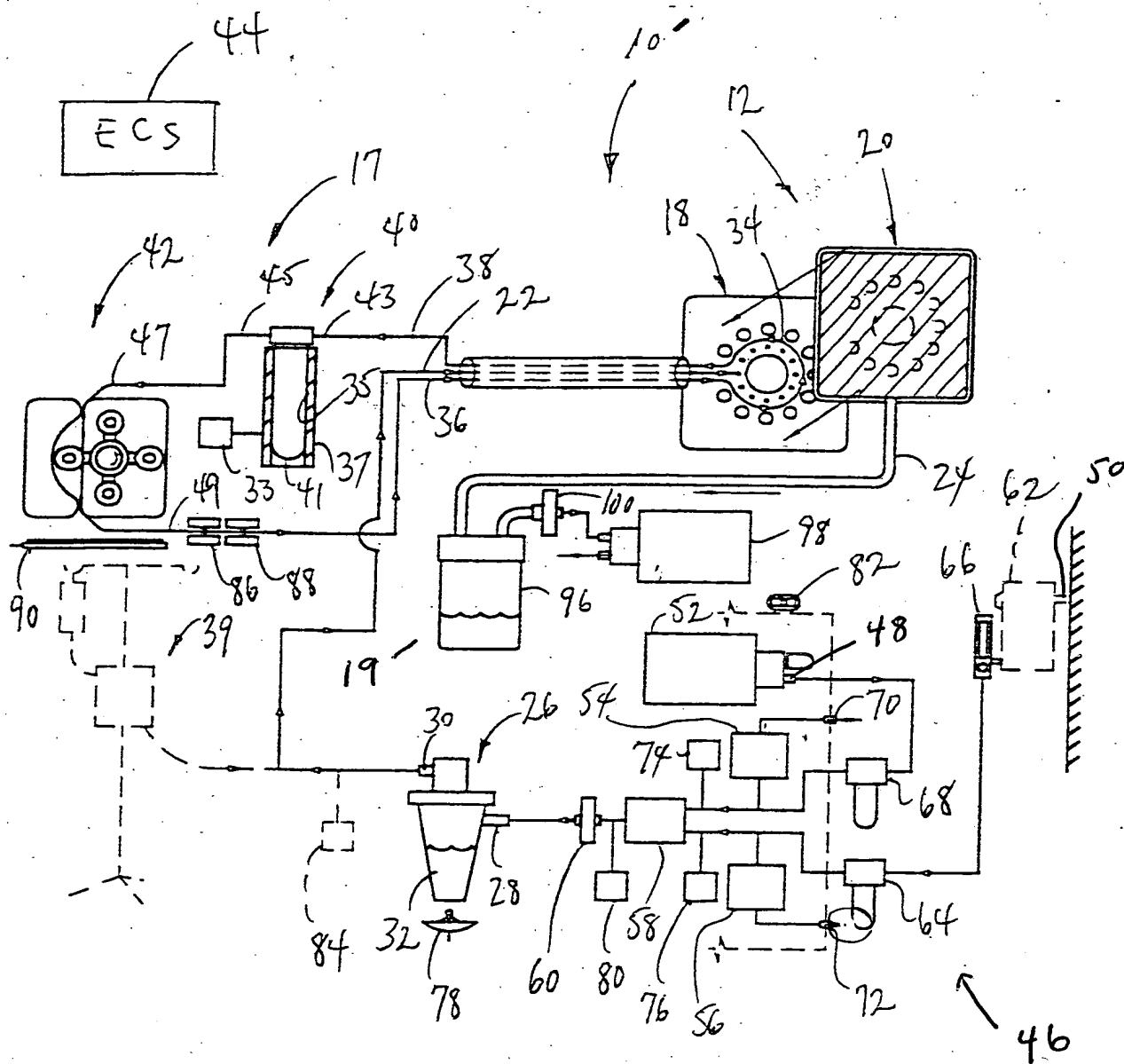


Fig. 3

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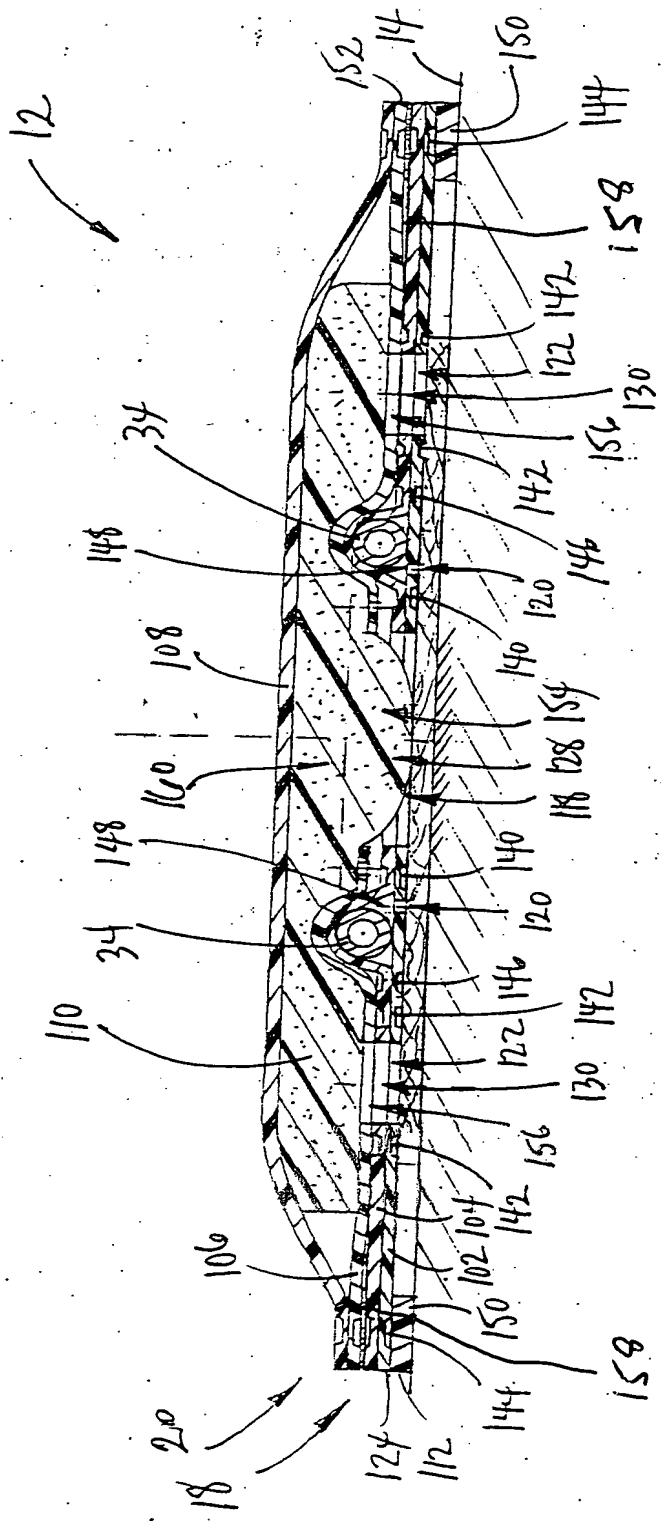


Fig. 9

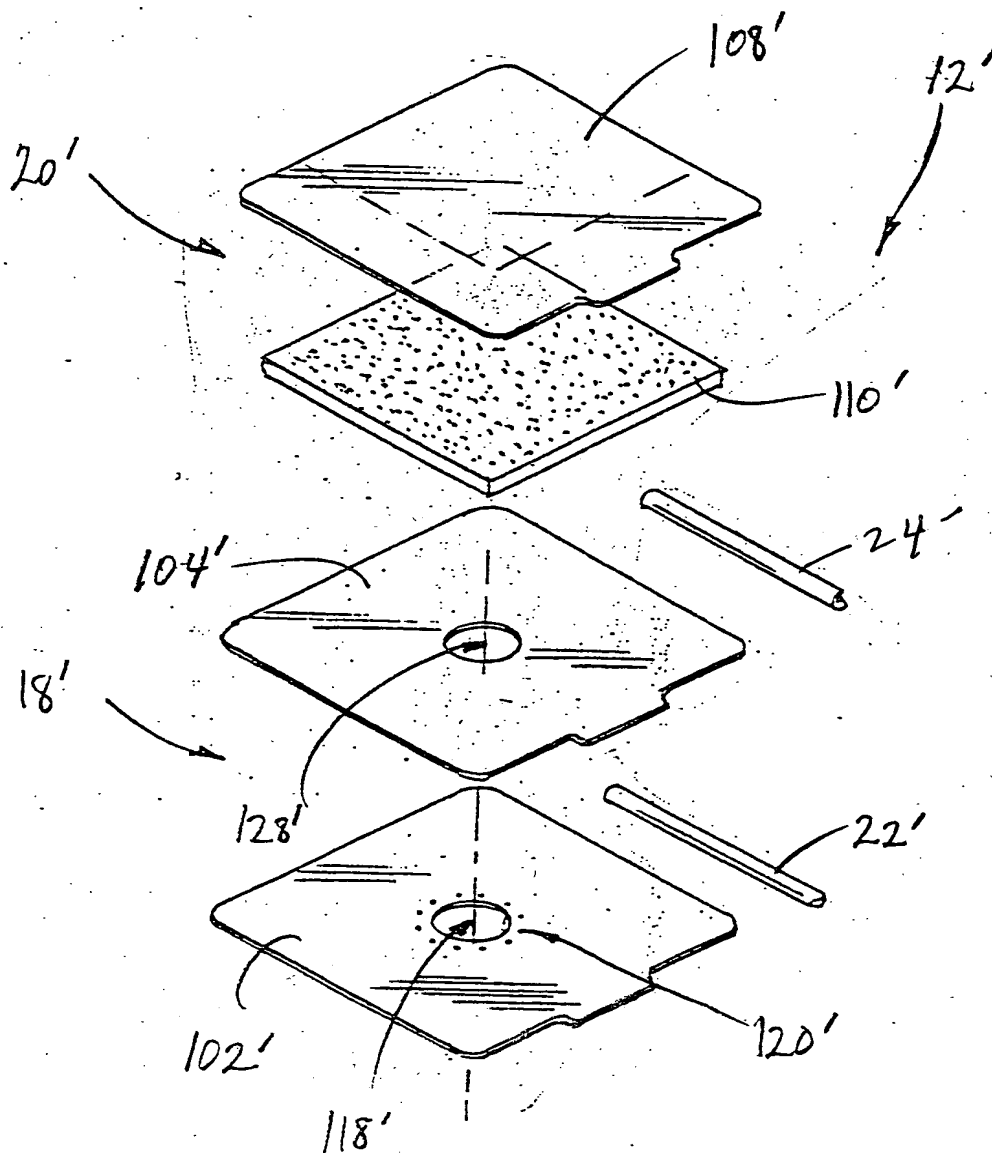


Fig. 11

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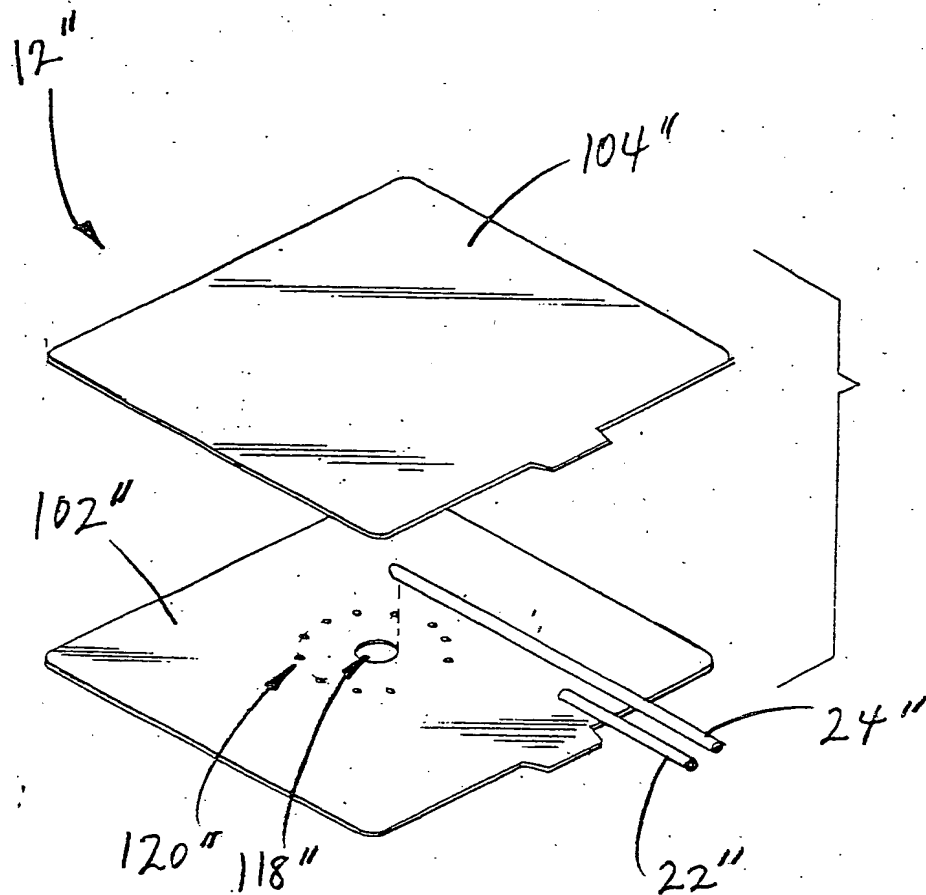


Fig. 12

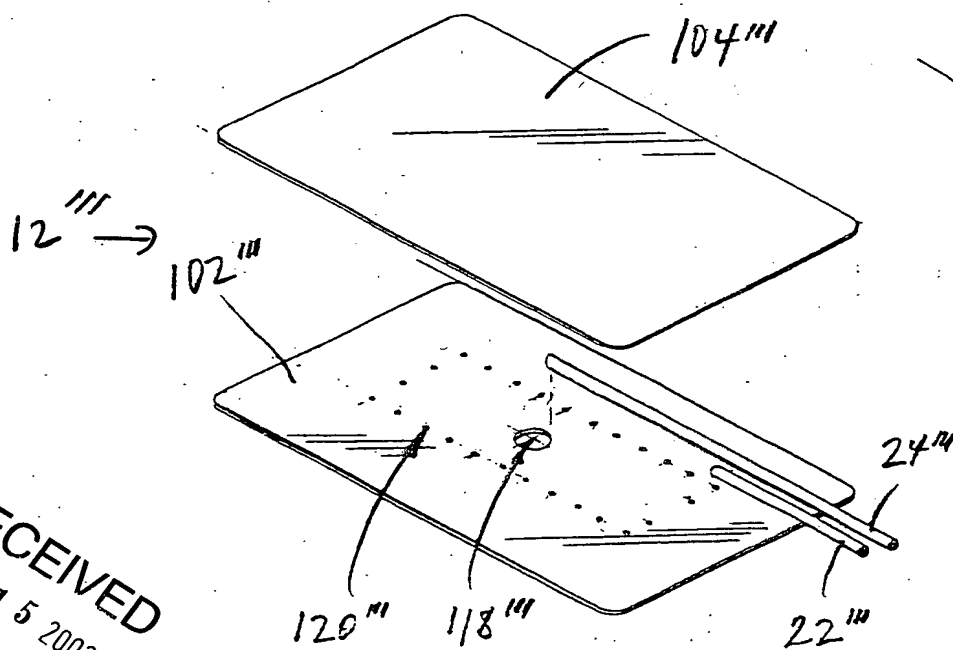
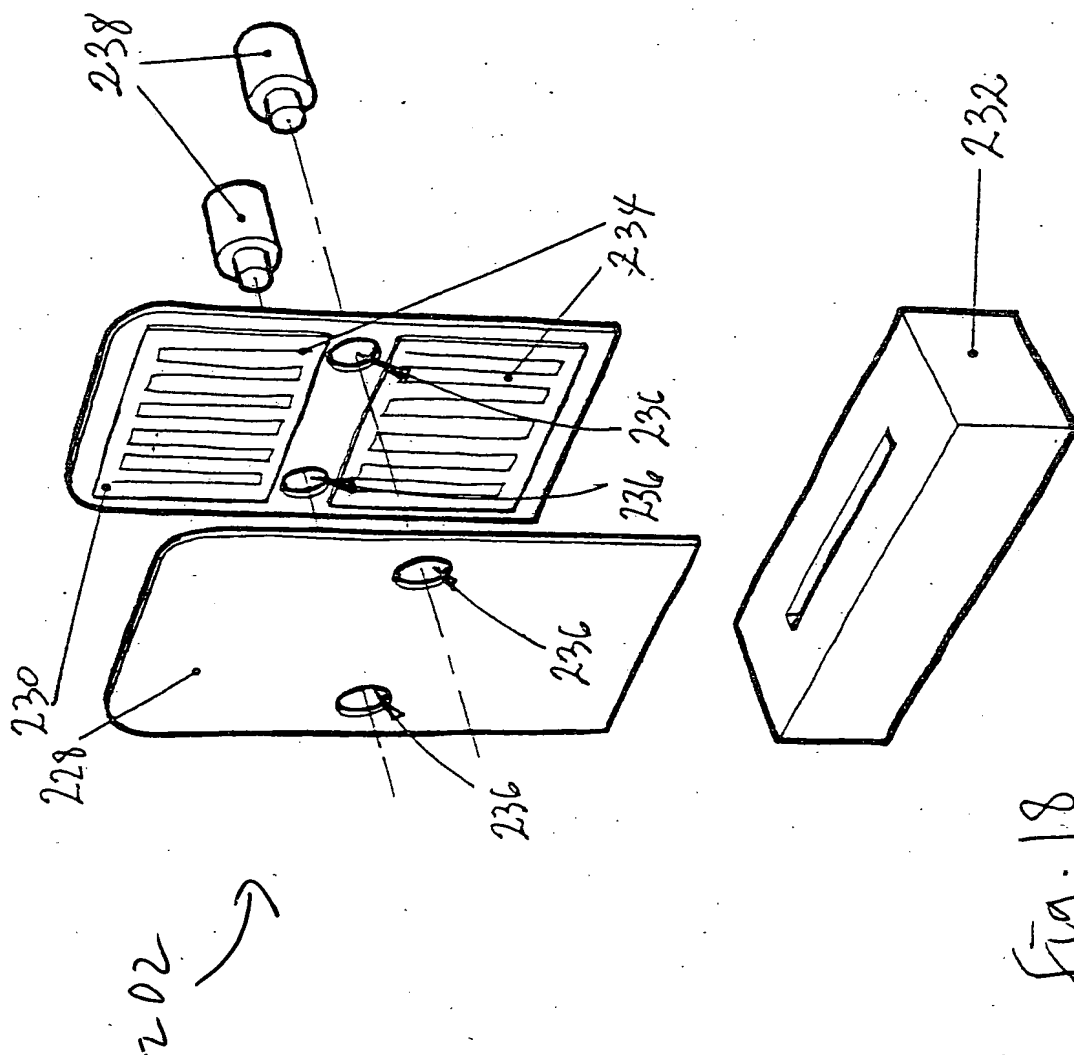


Fig. 13

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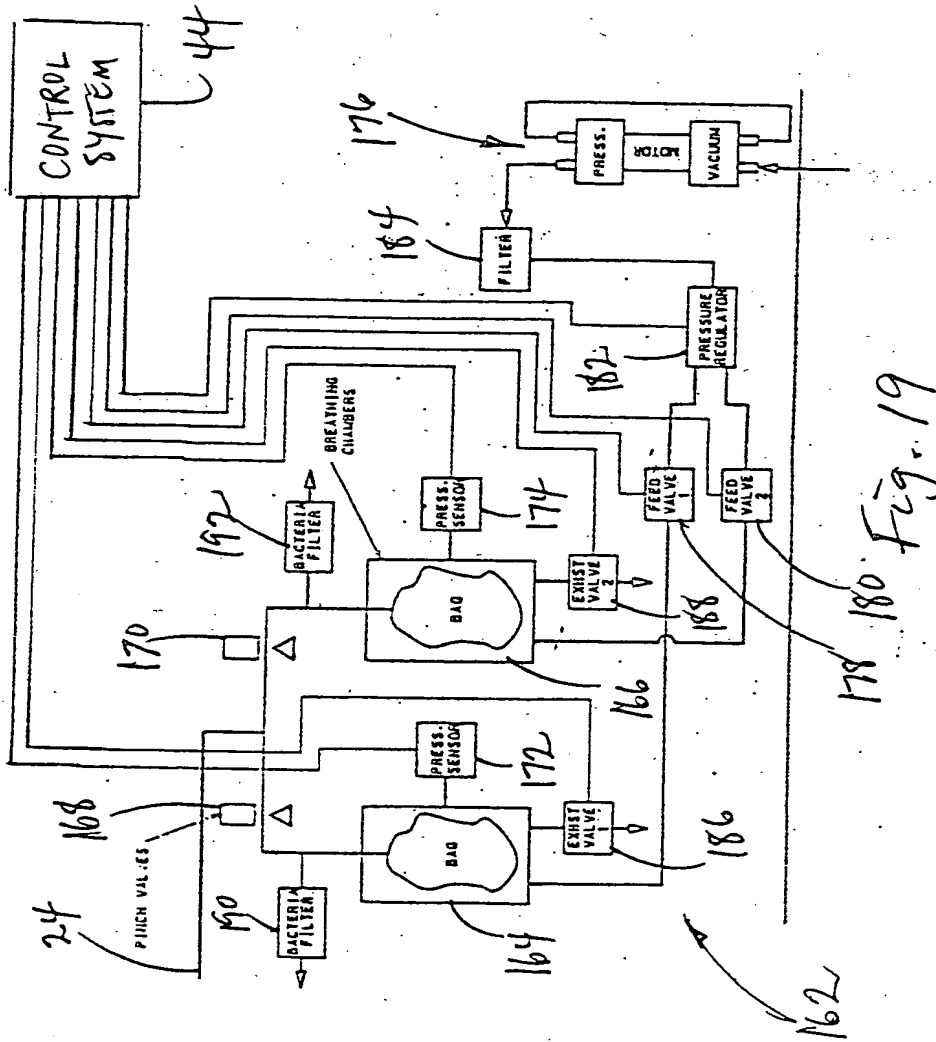


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Fig. 18



162



178 180 Fig. 19

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Fig. 27

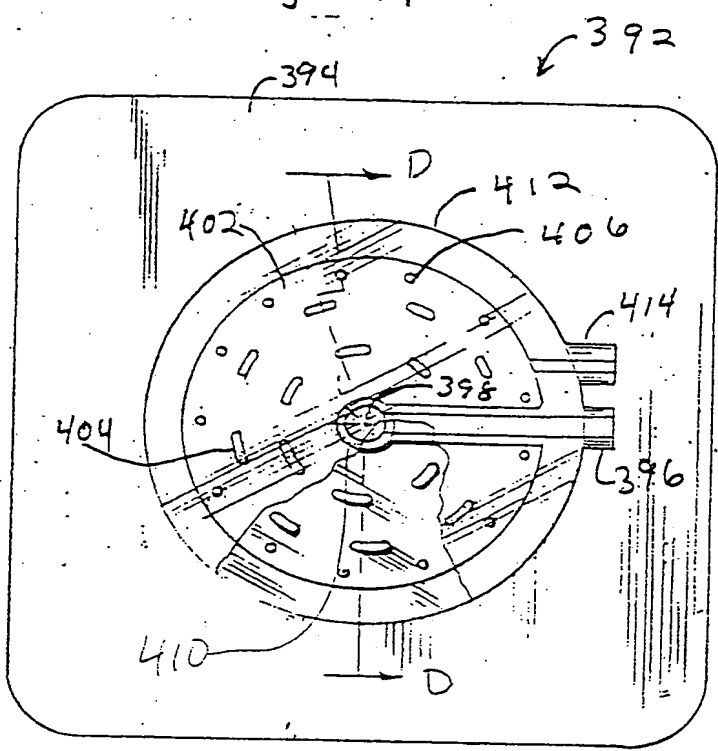


Fig. 28

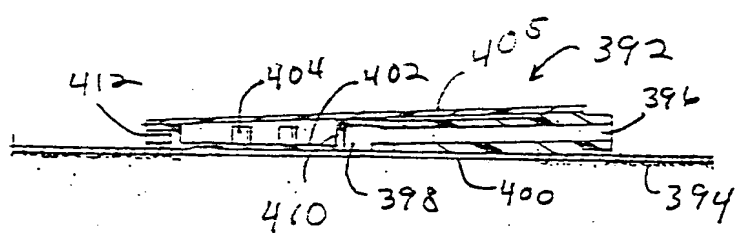
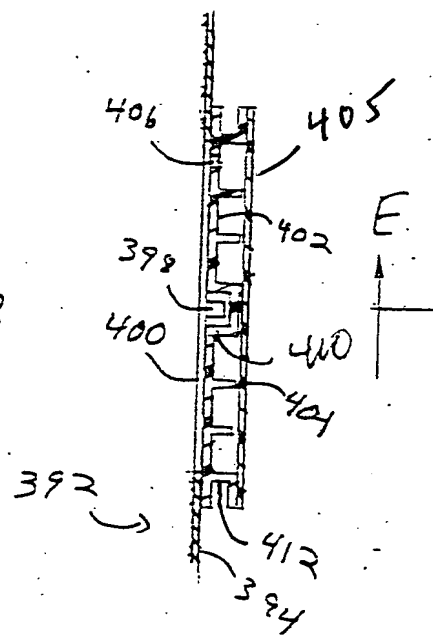


Fig. 29

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